and when used discriminately it benefit outweighs the possible risks. However, Government, with the help of an expert committee is investigating the rationality for continued marketing of combinations of Analgin with other drugs.

(f) It is not true that other pain killers moving in the market are totally free from side effects and every drug has its characteristic side effects.

(g) Does not arise.

**Marketing clearance for new drugs, drug combinations and vaccines**

488 SHRI M. KADHARSHA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that both clearance for marketing of new drugs, combination drugs and vaccines as well as manufacturing permissions are granted by State drug Authorities;

(b) if so, whether it is a fact that State drugs authorities are neither having qualified nor experienced officers to take a decision about the rationality or irrationality of drugs;

(c) what is the direction of the Government in regard to clearance of new drugs, combination of drugs and vaccines in the country;

(d) whether Government have proposed certain guideline in this regard; and

(e) if so, what are the details of the same?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) and (b) As per the "Guidelines on Introduction of New Drugs" combination of known drugs and vaccines would fall under the definition of "new drugs" and as such permission to market and manufacture new drugs is required to be granted by the Drugs Controller (India). However, the guidelines are not yet statutory and some States have cleared certain combinations of drugs and vaccines for marketing in consultation with their experts.

State Drug Control Authorities in consultation with experts generally license formulations.

(c) to (e) The "Guidelines on Introduction of New Drugs" gives a clear-cut definition as to what constitutes a new drug, defines the various phases of clinical trials, safety data and other pre-clinical data that are required to be submitted for examination before clinical trials permission could be granted to an applicant. Both pre-clinical and clinical data that are required to be submitted for a new drug for consideration of its marketing are also given in the guidelines. It also gives the types of data that are required for consideration of marketing permission of various possible types of combinations.

**Linking of Sector-37, NOIDA with Kendriya Terminal by D.T.C.**

489. SHRI M. KADHARSHA: Will the Minister of SURFACE TRANSPORT be pleased to state:

(a) whether representations have been received by D.T.C. authorities recently regarding linking of Sector-37, NOIDA with Kendriya Terminal, if so, the action taken by Government on each of such demand;

(b) whether Government propose to start some bus routes from that area for Kendriya Terminal in the near future; if so, by when; and

(c) if not, the reasons therefor?

THE MINISTER OF STATE OF THE MINISTRY OF SURFACE TRANSPORT (SHRI RAJESH PILOT): (a) to (c) Yes Sir. A trip at 0640 hrs. on Route No. 346 has been provided from Sector-37 NOIDA for Kendriya Terminal and vice-versa at 1315 hrs. There is no proposal for further augmentation as the existing service is considered adequate.